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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/595,096	06/15/2000	David J. Diller	1073.060	8927

23405 7590 11/26/2004

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5 COLUMBIA CIRCLE
ALBANY, NY 12203

EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/595,096

Applicant(s)

DILLER ET AL.

Examiner

Marjorie A. Moran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All rejections and objections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

A method, system and program comprising steps of identifying a ligand that binds to a protein are new. The originally filed claims were directed to a method, system and program for docking a ligand to a protein wherein multiple conformations of a (known) ligand were docked to hot spots of the protein. None of the originally filed claims recited identifying a ligand nor calculating a score predictive of the ligand binding to the protein. In the response filed 9/7/04, applicant points to various pages of the specification for support for the new claim limitations. Pages 17-20 disclose calculations of a score between two atoms in a comparison of particular conformations of a single ligand. The potentials calculated are used to determine "fit" of the different conformations, and the cutoff value disclosed on page 19 is a cutoff value for a potential. This cutoff value does not identify a single ligand as one which binds to the protein,

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but is merely used to screen out those conformations which do not “fit” into the hot spot (putative binding site) at all. Page 26 of the originally filed specification discloses that the scoring function of the inventive method is a filter to select docked conformations of a ligand; again, it is a tool to screen for those conformations of a single ligand which are likely to bind. The scoring function and associated cutoff are not disclosed anywhere as ones to actually identify a particular ligand as one which binds to a protein. The examples of the specification on pages 27-28 disclose search procedures for *generating* or *optimizing* conformations of KNOWN ligands for HIV protease which best fit or dock to HIV protease; i.e. those with the “top scoring docked position.” Page 31 clearly teaches that the inventive method is based on a pre-generated set of conformations for a (single) ligand, wherein a conformation of the ligand which “best” fits a binding site is generated. Calculation or generation of a conformation or conformations for an individual, **known**, ligand which fit into a binding site is not the same as identification of a (presumably unknown) ligand which binds to a protein. Optimization or selection of a conformation of a **known** ligand which best fits to a binding site has a “docking” score above a cutoff value is not the same as identifying a ligand which binds to a protein. In all cases taught by the instant specification, the ligand is known to bind to the protein and the intended result of the inventive method is used to calculate and/or generate different conformations of the ligand likely to bind to the protein.

For the reasons set forth above, applicant’s arguments are not persuasive and the claims are rejected for reciting new matter.

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In an effort to advance prosecution, applicant is advised that a method of ranking conformations and selecting a conformation or conformations of a ligand that are likely to bind to a binding site or hot spot of a protein MAY be considered statutory and MAY be useful; however, the claims do not recite ranking or selection of conformations.

Claim Rejections - 35 USC § 101

Applicant's arguments filed 9/7/04 have been fully considered but they are not persuasive. Applicant argues that as the claims recite "means plus function" language, they should be interpreted under 35 USC 112, sixth paragraph to construe the corresponding structure or material of the specification. In response, it is noted that the "means" may be program code. Page 4 of the specification discloses a program storage device tangibly embodying at least one program of instructions for performing the inventive method. If applicant intends the "means" to be the program storage device, then claims 11-20 are duplicative of claims 21-30. However, it appears (and is so interpreted by the examiner) that the "means" of claims 11-20 are actually the program of instructions. It is noted that applicant does not specifically point to disclosure (e.g. by page and line number) of any actual structure(s) corresponding to the recited functions of claims 11-20. Thus, even under a 112, sixth interpretation, the claims are directed to program instructions; i.e. program code, and do not recite an actual structure or device. For these reasons, the examiner maintains that the claims are directed to non-statutory subject matter and maintains the rejection.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722.

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The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
11/23/04